

## REMARKS

- This paper responds to the Final Office Action, dated April 1, 2009, and the Advisory Action, dated July 22, 2009.
- In the Advisory Action, the PTO stated that the Amendment After Final filed on July 8, 2009 has overcome the rejection of claim 48 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. *See* the fifth paragraph in the Advisory Action dated July 22, 2009. However, the Examiner alleged that Applicant's comments in the Amendment After Final are not persuasive and maintained the 35 U.S.C. § 103(a) rejections raised in the Final Office Action. *See* the continuation sheet of the Advisory Action dated July 22, 2009. The pending claims are 1, 3, 5-9, 11, 15, 22 and 41-47. The current pending rejections are:
  - rejected claims 1, 5, 11, 15, 22 and 41-47 under 35 U.S.C. § 103(a) as being unpatentable over Tsimberidou *et al.* (*Cancer Chemotherapy and Pharmacology* (2002) 50:237-242, “Tsimberidou *et al.*.”) in view of Man *et al.* (WO2001/34606, “Man *et al.*.”);
  - rejected claims 3 and 7-9 under 35 U.S.C. § 103(a) as being unpatentable over Tsimberidou *et al.* in view of Man *et al.* and Alter *et al.* (*Blood* (1985) 66:373-379, “Alter *et al.*.”); and
  - rejected claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Tsimberidou *et al.* in view of Man *et al.* and Canepa *et al.* (*British Journal of Haematology* (2001) 115:313-315, “Canepa *et al.*.”).

The Examiner alleged that even though the modes of action of Etanercept and Compound A are different, the end result is allegedly the same because both allegedly decrease the activity of TNF alpha, either by directly binding to it (Etanercept) or by decreasing the amount of TNF-alpha in circulation (Compound A). *See* the continuation sheet of the Advisory Action dated July 22, 2009.

The Applicant respectfully disagrees with the Examiner's allegation above because in order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on the mere fact that the components at issue are functional equivalents. *In re Scott*, 323 F.2d 1016, 139 USPQ

297 (CCPA 1963). Here, the examiner has not provided evidence to show that the equivalency of the two modes of action (*i.e.*, **action of binding** of TNF-alpha is equivalent to the **action of decreasing** the levels of TNF-alpha) has been recognized in the prior art. Actually, the Examiner has admitted that the two modes of action are different, and therefore not equivalent. *See* line 4 of the continuation sheet of the Advisory Action dated July 22, 2009. Because the two modes of action are different, the Applicant respectfully submits that the Examiner's allegation is merely based on the alleged fact that the the two modes of action at issue are functional equivalents, *i.e.*, providing the same "end result", without evidence showing that the equivalency of the two modes of action has been recognized in the prior art. Such reliance on equivalence as a rationale to support an obviousness rejection by the Examiner is expressly and legally prohibited under *In re Scott*.

In view of the above remarks, the Applicant respectfully requests the reconsideration of the Amendment After Final and the withdrawal of the above-mentioned rejections.

### **CONCLUSION**

In light of the above remarks, the Applicant respectfully requests that the PTO reconsider this application with a view towards allowance.

The fees for the and RCE (\$810.00) are submitted online using Jones Day Deposit Account No. 50-3013 (referencing order no. 501872-999085). No other fee is believed due for this submission. However, if any fees are required for the entry of this paper or to avoid abandonment of this application, please charge the required fees to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: September 23, 2009 /KAM W. LAW/  
by: Kam W. Law Reg. No. 44,205  
For: Anthony M. Insogna (Reg. No. 35,203)  
**Jones Day**  
222 East 41st Street  
New York, N.Y. 10017-6702  
Tel: 212-326-3778